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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/983,025	10/22/2001	Claus Oxvig	OXVIG=1A	7756

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EXAMINER
STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/983,025	OXVIG ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19,22-53,55-59 and 62-69 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19,22-53,55-59 and 62-69 are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

[1] Claims 1-19, 22-53, 55-59, and 62-69 are pending in the application.

[2] Applicant's amendment to claims 5-10, 17-19, 42, 53, 59, and 65-67, cancellation of claims 20-21, 54, and 60-61, and addition of claims 68-69 in Paper No. 1.5, filed January 14, 2002, is acknowledged.

[3] Applicant's amendment to the specification in Paper No. 6, filed January 14, 2002, is acknowledged.

[4] Receipt of Information Disclosure Statements filed as Paper Nos. 4, 7, and 8 is acknowledged.

[5] Receipt of a foreign priority document (PA 2000 01571) filed as Paper No. 9 is acknowledged.

[6] Receipt of a computer readable form (CRF) of the sequence listing, a paper copy thereof, a statement directing entry of the paper copy, and a statement that the CRF is identical to the paper copy, filed as Paper Nos. 13 and 14 is acknowledged.

[7] It is noted that claims 56-58, drawn to a method for identifying an agent, are improperly dependent upon claim 53, drawn to an inhibitory agent. In the interest of advancing prosecution, the claims have been grouped as though they depend from claim 55.

[8] Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has

become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Election/Restrictions

[9] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 26, 27, drawn to a purified polynucleotide, a recombinant DNA molecule, a host organism, a method for producing a polypeptide, classified in class 435, subclass 226.

II. Claims 12-19, drawn to an isolated polypeptide, classified in class 435, subclass 226.

III. Claims 22-25, drawn to an antibody and a method for producing an antibody, classified in class 530, subclass 387.9.

IV. Claim 53, drawn to an inhibitory agent, classified in class 514, subclass 789.

V. Claim 59, drawn to an enhancing agent, classified in class 514, subclass 789.

VI. Claims 28-29, drawn to a method for inhibiting and/or reducing expression of PAPP-A2, classified in class 435, subclass 91.1.

VII. Claims 30-33, 35, and 37-41, drawn to a method for detecting PAPP-A2 or measuring the level of PAPP-A2 by detecting a polypeptide, classified in class 435, subclass 7.1.

VIII. Claims 30-33 and 36, drawn to a method for detecting PAPP-A2 or measuring the level of PAPP-A2 by detecting a polynucleotide in the form of mRNA, classified in class 435, subclass 6.

IX. Claims 30-34, drawn to a method for detecting PAPP-A2 or measuring the level of PAPP-A2 by detecting PAPP-A2 specific protease activity, classified in class 435, subclass 23.

X. Claims 42-47, drawn to a method of diagnosing a clinical condition by detecting a polypeptide, classified in class 435, subclass 7.1.

XI. Claims 42-47, drawn to a method of diagnosing a clinical condition by detecting a polynucleotide in the form of mRNA, classified in class 435, subclass 6.

XII. Claims 42-47, drawn to a method of diagnosing a clinical condition by detecting PAPP-A2 specific protease activity, classified in class 435, subclass 23.

XIII. Claim 48, drawn to a method for detecting expression of a polynucleotide, classified in class 435, subclass 6.

XIV. Claims 49-52, drawn to a method of identifying an agent inhibiting PAPP-A2 protease activity, classified in class 435, subclass 23.

XV. Claims 55-58, drawn to a method of identifying an agent enhancing PAPP-A2 protease activity, classified in class 435, subclass 23.

XVI. Claim 62, drawn to a method for purifying PAPP-A2 using an antibody, classified in class 530, subclass 413.

XVII. Claims 63-67, drawn to a method of diagnosing a clinical condition or predisposition to a clinical condition by measuring the level of a complex, classified in class 435, subclass 7.1.

XVIII. Claim 68, drawn to a method of treating a clinical condition mediated by IGFBP-5 by administering a polypeptide, classified in class 514, subclass 2.

XIX. Claim 69, drawn to a method of treating a clinical condition mediated by PAPP-A2 by administering a PAPP-A2 enhancing agent, classified in class 514, subclass 789.

[10] The inventions are distinct, each from the other because:

[11] The polynucleotide of Group I, the polypeptide of Group II, the antibody of Group III, the inhibitory agent of Group IV, and the enhancing agent of Group V each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotide of Group I has other utility besides encoding polypeptides such as being used as a hybridization probe, the polypeptide of Group II can be made by a method other than by the method of Group I such as purification from the natural source or chemical synthesis, and the antibody of Group III can be made by a polypeptide other than the polypeptide made by the method of Group I, such as a polypeptide purified from the natural source or chemically synthesized.

[12] The polynucleotide of Group I is unrelated to the method(s) of Groups VII, IX, X, XII, and XIV-XIX as it is neither used nor made by the method(s) of Groups VII, IX, X, XII, and XIV-XIX.

[13] The polynucleotide of Group I and the methods of Groups VI, VIII, XI, and XIII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I can be used for protein expression.

[14] The polypeptide of Group II is unrelated to the method(s) of Groups VI, VIII, and XIII, as it is neither used nor made by the method(s) of Groups VI, VIII, and XIII.

[15] The polypeptide of Group II and the methods of Groups VII, IX-XII, and XIV-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used as an antigen in the production of antibodies.

[16] The antibody of Group III is unrelated to the method(s) of Groups VI, VIII, IX, XII-XV, XVIII, and XIX as it is neither used nor made by the method(s) of Groups VI, VIII, IX, XII-XV, XVIII, and XIX.

[17] The antibody of Group III and the methods of Groups VII, X, XI, XVI, and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used to inhibit the polypeptide of Group II.

[18] The inhibitory agent of Group IV is unrelated to the method(s) of Groups VI-XIII and XV-XIX as it is neither used nor made by the method(s) of Groups VI-XIII and XV-XIX.

[19] The inhibitory agent of Group IV and the method of Group XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the inhibitory agent of Group IV can be used as an affinity reagent in the purification of the polypeptide of Group II or alternatively, for detecting the presence of the polypeptide of Group II.

[20] The enhancing agent of Group V is unrelated to the method(s) of Groups VI-XIV and XVI-XVIII as it is neither used nor made by the method(s) of Groups VI-XIV and XVI-XVIII.

[21] The enhancing agent of Group V and the methods of Groups XV and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the enhancing agent of Group V can be used as an affinity reagent in the purification of the polypeptide of Group II.

[22] The methods of Groups VI-XIX are independent as they comprise different steps, utilize different products and/or yield different results.

[23] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-XIX are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text and/or sequence search for each Group and thus, co-examination of the inventions of Groups I-XIX would place a serious burden on the examiner.

[24] It is noted that claims 30-33 and 42-47 will be examined only to the extent the claims read on the elected subject matter.

[25] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[26] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652

08/25/03